UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff,

Civil Action No.

v.

ACACIA MENTAL HEALTH CLINIC, LLC, and ABE FREUND,

Defendants.

COMPLAINT

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1. The plaintiff, United States of America ("United States"), brings this action against Acacia Mental Health Clinic, LLC ("Acacia"), and its owner, Abe Freund, under the False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA") to recover losses and penalties resulting from the submission of false claims for payment to the Wisconsin Medicaid program and under the common law theory of unjust enrichment.

2 Since at least 2011, Acacia and Freund pursued a scheme to defraud the Wisconsin Medicaid program. Acacia provides services to Wisconsin Medicaid members who suffer from mental health and substance abuse problems. However, at Freund's direction, Acacia used these vulnerable individuals as tools to bilk Medicaid for Freund's personal gain.

3. Freund, who has no background providing health care, purchased Acacia in 2009 and promptly worked to inflate Acacia's Medicaid billings. Medicaid pays for urine drug screens to test members for drug use, but only as a treating physician deems it necessary in individual cases. Without regard to necessity, Freund ordered that Acacia bill Medicaid for urine

drug screens for a wide array of tests on every patient. From January 2011 until October 2012, Acacia routinely submitted false claims that resulted in a $230 reimbursement for each drug screen when the proper reimbursement was only approximately $20 – and Acacia's cost for the test was just $5. From there, Acacia's scheme grew aggressively so that, by 2013, Acacia was obtaining an average of $474.66 per testing event. Based in large part on these false billings, Acacia's overall Wisconsin Medicaid reimbursement grew from about $332,000 in 2011 to about $3.3 million in 2014, for a total of over $7.3 million from 2011 to 2014.

4. Freund and Acacia's misconduct extended beyond subjecting patients to needless urine drug screens for personal gain. Despite knowing that Medicaid prohibited payments to providers who were located outside the United States, they also billed Wisconsin Medicaid for telemedicine services provided by psychiatrists located in Israel.

5. The United States alleges that Freund and Acacia violated the FCA by knowingly submitting false or fraudulent claims for payment to Wisconsin Medicaid for services that were misrepresented on the applicable claim forms, duplicative, not medically necessary, and/or otherwise performed in violation of the Medicaid rules.

I. JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1345 because the action is brought by the United States as plaintiff pursuant to the FCA. The Court has supplemental jurisdiction to entertain the common law cause of action for unjust enrichment under 28 U.S.C. § 1367(a).

7. The Court has personal jurisdiction over Acacia and Freund, and venue is appropriate in this Court pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b), because

Acacia and Freund transacted business in the Eastern District of Wisconsin and caused false claims to be submitted in this District.

II. PARTIES

8. The plaintiff in this action is the United States, suing on its own behalf and on behalf of its operating division, the Department of Health and Human Services ("HHS") and HHS's component agency, the Centers for Medicare & Medicaid Services ("CMS").

9. Acacia is a Wisconsin limited liability corporation with a principal place of business at 5228 West Fond du Lac Ave, Milwaukee, Wisconsin. Acacia is a mental health and substance abuse clinic that provides services to Medicaid members including, but not limited to, counseling and medication management services by licensed healthcare providers such as psychiatrists and advance practice nurses and counseling services provided by professional counselors.

10. Defendant Freund is a citizen of the United States who resides in Monroe, New York and, at all times relevant to the complaint, was owner and chief executive officer of Acacia. Freund was involved in the day-to-day operations of Acacia, including establishing and overseeing policies and procedures for the clinic, its urine drug testing services, and the billing of services to third party payers, including the Wisconsin Medicaid Program.

III. THE FALSE CLAIMS ACT

11. The FCA provides, in part, that any entity that (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim, is liable to the United States for damages and penalties. 31 U.S.C. §§ 3729(a)(1)(A)-(B).

12. The term "knowingly" under the FCA means that a person, with respect to information, (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required to show that person acted knowingly under the FCA. *Id.*

13. Violations of the FCA subject the defendant to civil penalties of not less than $5,500 and not more than $11,000 per false claim plus three times the amount of damages that the Government sustains as a result of the defendants' actions. 31 U.S.C. § 3729(a).

IV. THE MEDICAID PROGRAM

14. Medicaid is a program jointly funded by the federal government and participating states to provide health insurance to indigent families with dependent children and to aged, blind, and disabled individuals whose income and resources are insufficient to meet the cost of medical services. 42 U.S.C. §§ 1396, *et seq*. (the "Medicaid Act"). The Medicaid Act sets forth minimum requirements for state Medicaid programs to meet in order to qualify for federal funding and each participating state adopts its own state plan and regulations governing the administration of the state's Medicaid program.

15. Wisconsin participates in the Medicaid program ("Wisconsin Medicaid"). In Wisconsin, the Medicaid program was established pursuant to Wisconsin Statutes Chapter 49 and its administrative regulations. The United States pays for approximately 63% of the program.

16. Wisconsin Medicaid provides reimbursement for health care services provided to eligible individuals who are enrolled in the program. To assist with the administration of the

Medicaid Program, Wisconsin contracts with a company, HPE, which is responsible for processing and paying claims submitted on behalf of the Medicaid members.

17. In order to submit claims to Wisconsin Medicaid for health care services provided to its members, a provider must enter into a written Medicaid Provider Agreement with the Wisconsin Department of Health Services. Providers that are accepted into the Medicaid Program, and who have signed a Medicaid Provider Agreement, are referred to as "certified" providers.

18. Freund, on behalf of Acacia, signed a Medicaid provider agreement in 2009. Among other things, Freund, and thereby Acacia, agreed to the following:

> Provider acknowledges that the restrictions and conditions listed in this section govern its participation as a provider in Wisconsin Medicaid:
>
> a. Provider is subject to certain requirements and restrictions under state and federal laws in addition to those referred to in Section 1. above, as well as applicable Wisconsin Medicaid provider publications.
>
> The Provider further acknowledges that by submitting claims as a Wisconsin Medicaid provider, the Provider becomes subject to the foregoing and all other applicable Wisconsin Medicaid restrictions and conditions.

19. One of the conditions of the Wisconsin Medicaid Program is that it only covers, and reimburses for, services that are "medically necessary" and "appropriate." Wis. Admin. Code DHS §§ 106.02(5) and 107.01. The term "medically necessary" is defined by Wisconsin Medicaid to include only services that are "not duplicative with respect to other services being provided to the recipient. . . ." DHS § 101.03(96m)(b)(6).

20. Further, the Wisconsin Medicaid Program will not pay for services that "fail to comply with program policies or state and federal statutes, rules and regulations. . . ." Wis. Admin Code DHS § 107.02(2)(a).

V. PAYMENT OF CLAIMS BY WISCONSIN MEDICAID

21. Medicaid providers may submit claims for reimbursement to Wisconsin Medicaid either on paper or electronically.

22. Medicaid providers are responsible for the truthfulness, accuracy, timeliness and completeness of all claims submitted to Medicaid. Wis. Admin. Code DHS § 106.02(9)(e). To certify to the accuracy and completeness of a claim, claims must be signed by the provider. Wis. Admin. Code DHS § 106.03(2)(d).

23. Claims are submitted to Wisconsin Medicaid using a standardized claim form known as the 1500 Health Insurance Claim Form. When submitting a claim to Wisconsin Medicaid with that form, the provider must sign and date the form. By doing so, the provider certifies that "the services listed above were medically indicated and necessary to the health of this patient. . . ." Further, by submitting a claim to Wisconsin Medicaid, the provider further certifies:

> [T]he foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal and State laws.

24. In order to be permitted to submit claims electronically to Wisconsin Medicaid, providers must enter into an agreement with Wisconsin Medicaid called a Trading Partner Agreement. The provider's signature on the Trading Partner Agreement substitutes for the required signature and certification of the accuracy and completeness of each electronic claim. Wis. Admin. Code DHS §106.03(2)(d).

25. Acacia entered into a Trading Partner Agreement with Wisconsin Medicaid and, as a result, submitted claims electronically to Medicaid and thereby certified to the accuracy and completeness of the claims.

26. When submitting a claim for services to Wisconsin Medicaid, the provider designates a numeric code assigned to that service or procedures by the American Medical Association. These codes are known as Current Procedural Terminology, or CPT codes, and are used by health care providers to represent what services have been provided and for which they are seeking reimbursement.

27. In addition, CMS has assigned and published numeric codes for supplies and services that supplement the CPT codes. This coding system is known as the Healthcare Common Procedure Coding System, or HCPCS. HCPCS codes are similarly used by health care providers to represent what services have been provided and for which they are seeking reimbursement.

28. To submit claims to Wisconsin Medicaid, providers must include a CPT or HCPCS code on the claim that accurately represents the service provided or the procedure performed.

29. In addition, providers must include a numeric code on the claim that represents the diagnosis for which the member is being treated. That diagnosis is documented on the claim by a code selected from the International Classification of Diseases, or ICD-9 code, which is overseen by the National Center for Health Statistics and CMS. To submit claims to Wisconsin Medicaid, providers must include an ICD-9 code that accurately represents the patient's diagnosis.

VI. ACACIA AND FREUND'S FALSE CLAIMS FOR URINE DRUG SCREENS

30. Since at least 2011, Acacia has routinely submitted false claims to Wisconsin Medicaid for urine drug testing known as urine drug screens ("UDS"). Acacia administered

these tests purportedly to determine whether patients were taking any illegal substances and to verify they were taking their prescribed medications. Many of the claims submitted by Acacia to Wisconsin Medicaid for UDSs were false because Acacia (1) misrepresented the nature of the test being performed; (2) failed to record or maintain any results from the test; (3) misrepresented the number of tests being performed; and/or (4) performed a test for which there was no medical need.

31. In order to perform laboratory tests such as UDSs in a clinic, a healthcare provider must first be certified pursuant to the Clinical Laboratory Improvements Act (CLIA). For purposes of CLIA certification, a provider may either obtain a certificate of waiver, which permits the provider to perform very simple tests in the clinic, or it may obtain a certificate of accreditation, which allows the provider to perform more complex testing in the clinic.

32. Urine drug screens include two different types of tests. The first type of test produces "qualitative" or "presumptive" results; that is, the results indicate that the sample is positive or negative for specified classes of drugs. These tests can be performed under a certificate of waiver or a certificate of accreditation, depending on the equipment and the methodology used.

33. The second type of test produces "quantitative" or "definitive" results; that is, the results indicate the specific substance or drug and the quantity of the substance or drug in the sample. The quantitative test is a more sophisticated test that requires the laboratory to use costly, high-complexity equipment. In order to perform these types of tests in a medical clinic, the clinic must possess a CLIA certificate of accreditation.

34. While UDSs can play an important role in mental health and substance abuse treatment, a physician must make an individualized, patient-specific determination about the

frequency of testing and the types of drugs to be tested in order for the testing to be considered medically necessary. See e.g., *Drug Testing: A White Paper of the American Society of Addiction Medicine (2013); Public Policy Statement on Drug Testing as a Component of Addiction Treatment and Monitoring Programs and in Other Clinical Settings*, American Society of Addiction Medicine (2010). Because the drug testing must be tailored to each patient's particular medical needs, standard panels of tests and testing at set intervals (such as at every designated office visit) are not medically necessary.

35. Starting in at least 2010, Freund mandated that (1) every Acacia patient was required to "drop" a urine drug sample every time the patient had an appointment with a prescriber (typically either a physician or advance practice nurse) at the clinic or had a group therapy session and (2) each patient be tested for the same panel of drugs. Freund's policy did not take into account the treating physician's clinical judgment or the diagnosis or history of the patient. Among other things, Freund's drug testing policy did not distinguish between patients with substance abuse disorders and those with mental health diagnoses.

36. Because Acacia physicians did not make individualized determinations about the need for UDS testing or the frequency based on the patient's diagnosis and history, many of the UDSs billed by Acacia to the Medicaid program were not medically necessary.

A. False Claims January 2011 – October 2012

37. From January 2011 until October 2012, Acacia had a CLIA certificate of waiver to enable it to perform certain types of UDS.

38. From January 2011 to October 2012, Acacia administered a qualitative or presumptive test that utilized specimen cups, referred to as "Point of Care" or "POC" cups. These cups identify only the presence or absence of several drug classes but do not identify

specific drugs or the quantities of those drugs in the urine. Because each cup is able to identify whether multiple drug classes are present in the sample simultaneously and in one procedure, they are referred to as "multiplexed" screening tests or kits. Determining the results of the test simply involves a staff person of the clinic, who needs little special training, to read the results on the side of the cup with no additional equipment needed. These tests may be performed by providers who have a CLIA certificate of waiver.

39. The cost of each POC cup to Acacia was approximately $5.00.

40. During the time period at issue, UDSs performed with POC cups were properly billed to Wisconsin Medicaid by describing the test using either CPT code 80104 or HCPCs code G0434. The description of CPT code 80104 was a qualitative drug screening test for "multiple drug classes. . ., each procedure." The description of HCPCs code G0434 was "Drug screen, other than chromatographic; any number of drug classes, by CLA waived test or moderate complexity test, per patient encounter." The Wisconsin Medicaid reimbursement associated with the tests using either of these codes was approximately $20 per test.

41. During this time, it was not proper to bill for UDSs done by POC cups using CPT code 80101. The description of code 80101 was a qualitative drug screen test using a "single drug class method. . . each drug class." Because CPT code 80101 reflects tests of individual drugs classes, providers were permitted to bill one unit for each drug class tested. However, the AMA issued a specific directive that code 80101 excluded testing "multiple drug classes or drug class by multiplexed screening kits" and stated that those tests were covered by CPT code 80104.

42. Acacia submitted thousands of false claims to Wisconsin Medicaid for these POC tests performed with POC cups. Rather than accurately describing these POC cup tests using either CPT code 80104 or HCPCS code G0434, Acacia improperly used CPT code 80101 to

describe the tests and billed multiple units for each drug class included on the cup. By using CPT code 80101, Acacia misrepresented that it performed more complex tests than what it actually performed. Each time Acacia billed Medicaid for a test performed in a POC cup during this time period, it improperly billed the test using CPT code 80101 and falsely represented that it had performed between 12 and 14 units of that code (representing that it had performed separate tests for 12 to 14 drug classes).

43. Between January 2011 and October 2011, Acacia received approximately $230 in reimbursement from the Medicaid program each time it submitted a false claim for these tests under CPT code 80101. Between November 2011 and October 2012, Acacia increased the number of units billed from 12 to 13, and then to 14, units under CPT code 80101 and, thereby, increased its average reimbursement for each test from about $230 to about $253.

B. False Claims from November 2012 – August 2013

44. In January 2012, Acacia received a certificate of accreditation pursuant to CLIA, allowing it to conduct presumptive or qualitative testing using more complex drug analyzing equipment.

45. In November 2012, in addition to using the POC cups, Freund purchased a desk-top analyzer (the Siemen's "VivaE analyzer") for Acacia to perform qualitative drug tests in the clinic. In order for a clinic to perform tests using this type of analyzer, it must possess a CLIA certificate of accreditation.

46. The cost to Acacia for the VivaE analyzer was approximately $40,000.

47. While the VivaE analyzer was able to detect lower levels for the drug classes being tested than the POC cups, the analyzer used the same technology as the POC cups and similarly identified multiple drug classes in a single test procedure. The VivaE analyzer also

produced results similar to the POC cups – that is, the results indicated whether a sample was positive or negative for a class of drugs and did not identify a specific drug detected in the sample or the quantity of the drug in the sample.

48. After purchasing the VivaE analyzer, Acacia began to perform and bill Medicaid for two sets of tests using the same technology during the same patient encounter: one using the POC cups, and the other using the VivaE analyzer. Because the tests were performed for the same purpose and generated similar results, they were duplicative and not medically necessary.

49. Performing and billing tests with the VivaE analyzer was not medically necessary unless a physician identified a need to test for drugs with lower identification limits and/or to test for a drug or drug class that was not able to be tested with a POC cup.

50. The electronic claims software used by Wisconsin Medicaid rejected claims that had certain pairs of codes billed together by the same provider on the same day. For example, the claims system would reject a claim that included both 80101 and 80104 or both G0431 and G0434 on the same date of service for the same member because each code pair represented qualitative or presumptive testing using the same technology.

51. In order to avoid having the claims for these duplicative services denied by the Medicaid billing system, Acacia and Freund opted to use HCPCS code G0434 for the tests performed with the POC cups and CPT code 80101 for the tests run on the VivaE analyzer. Acacia chose this particular pair of codes because the misuse of code 80101 allowed Acacia to bill for up to sixteen individual drug classes, or units, for every test, thereby significantly increasing the reimbursement for the tests.

52. By billing both tests, Acacia was again able to increase its average reimbursement for each testing event, which included one POC cup and one test on the VivaE analyzer, to approximately $310.

53. Despite the fact that Freund and Acacia chose to bill Wisconsin Medicaid for duplicative tests, when submitting claims to Wisconsin Medicaid Acacia and Freund expressly certified that these services were medically indicated and necessary.

54. Between November 2012 and August 2013, Acacia submitted thousands of false claims to Wisconsin Medicaid for duplicative urine drug tests performed with both the VivaE analyzer and the POC cups. Additionally, many of these tests were not medically necessary because a physician did not order the UDSs, and because no physician made an individualized determination as to the appropriate frequency of the testing or as to the drugs to be tested based on the patient's diagnosis and history.

C. False Claims from September 2013 – December 2014

55. In addition to continuing the false billings described above, in about August 2013, Freund obtained an additional analyzer (the AbSciex Triple Quad 4500-AMCR, or Triple Quad) for Acacia to process quantitative tests in-house. In order for a clinic to perform tests with this analyzer, it must possess a CLIA certificate of accreditation.

56. Acacia's cost for the Triple Quad analyzer was approximately $200,000.

57. In about December 2013, Freund obtained a second quantitative analyzer (the AbSciex Q Trap 4500-AMCR, or QTrap) for Acacia to process quantitative tests.

58. Acacia's cost of the QTrap analyzer was approximately $220,000.

59. Freund purchased both the Triple Quad and the QTrap analyzers so that Acacia could perform quantitative tests in-house and bill Wisconsin Medicaid for those tests, rather than send samples to a third-party lab that billed Wisconsin Medicaid directly for those tests.

60. Confirmatory or quantitative testing is medically necessary only when a physician identifies a specific need for additional testing and the specific substances for which there is a clinical benefit to confirm or quantify. Confirmatory or quantitative tests are, therefore, not medically necessary following all qualitative urine drug screens.

61. Since at least August 2013 when Acacia acquired the first quantitative analyzer, Freund required that Acacia employees perform quantitative or confirmatory testing on **all** urine samples, regardless of whether the result of the original test was positive or negative. Although Acacia employed several physicians, there was no physician involvement in ordering these tests for Acacia patients or in determining which substances were tested. Moreover, Acacia utilized a standard panel of tests for all samples; that is, Acacia performed the same quantitative or confirmatory test on each sample without regard to patient history or the results of the qualitative or presumptive test.

62. Despite the fact that Freund and Acacia required all patient samples be quantitatively tested for a set panel of drugs without a physician's determination that the testing was indicated and necessary, Acacia and Freund expressly certified by submitting claims to Wisconsin Medicaid that the services billed for on the claims were medically indicated and necessary.

63. Acacia also billed Wisconsin Medicaid for quantitative tests for which there is no evidence in the clinical record that the test was performed.

64. Acacia submitted thousands of false claims to Wisconsin Medicaid for quantitative or confirmatory testing because (1) Acacia and Freund's policy failed to take into account a physician's independent judgment about the need for quantitative testing or the particular substances to be tested, or (2) the clinical record contained no evidence that such a test had been performed.

D. Acacia and Freund's Knowledge of the Billing Requirements and the False Claims

65. Acacia and Freund knew that the claims submitted to the Wisconsin Medicaid Program for urine drug screens were false or they acted in deliberate ignorance or reckless disregard of the truth or falsity of such claims.

66. Between 2011 and 2014, Acacia received the following reimbursement from Wisconsin Medicaid for urine drug testing:

Year	UDS - Number of Claims	UDS – Medicaid Reimbursement
2011	1,558	$179,191.08
2012	3,521	$757,854.26
2013	7,611	$1,992,813.15
2014	8,997	$2,959,545.84
Total	**21,687**	**$5,889,404.33**

67. As a certified Medicaid provider, Freund and Acacia had a duty to understand Medicaid's billing rules and requirements and to submit claims to Wisconsin Medicaid that were accurate and truthful.

68. Between 2011 and 2014, Acacia billed Wisconsin Medicaid for vastly more urine drug screens than any other mental health provider in the State of Wisconsin. In fact, Acacia's

reimbursement from Wisconsin Medicaid accounted for 99% of all Medicaid reimbursement provided to mental health and substance abuse providers in the State of Wisconsin during those years.

69. Since 2009, Acacia has employed an individual, Malkah Wajchman, to perform billing for Acacia, including billing to Wisconsin Medicaid. Ms. Wajchman is trained in medical billing and coding and received a certificate as a "billing and coding specialist" from the American Healthcareer Association. Under Freund's supervision, Ms. Wajchman coded Acacia's claims to insurance carriers and Medicaid and submitted the resulting bills.

70. In 2010, the AMA and CMS published guidance about the changes to both the CPT codes and the HCPCS codes for urine drug testing, which became effective January 1, 2011. Among other things, the AMA's publication "CPT Assistant" published in December 2010 (Volume 20, Issue 12, p. 7) discussed the introduction of CPT code 80104. The article discussed that, under older drug testing technology, urine drug screen tests could test for just one class of drugs in each test and each test was appropriately billed using CPT code 80101. Because a provider may have had to conduct multiple tests, each test was billed as a unit. When the technology advanced to allow for the testing of multiple classes of drugs with one test (multiplexed POC tests), it was no longer appropriate to bill multiple units under CPT code 80101. As a result, CPT code 80104 was created "to describe a non- chromatographic method wherein multiple drugs classes were screened in a single procedure. . . ."

71. In 2010, CMS also stopped paying claims submitted to Medicare with CPT code 80101 and, effective January 1, 2011, instituted two new HCPCS codes to replace CPT code 80101. HCPCS code G0434 was introduced to report very simple tests, such as POC cups, and other types of drug tests that were designated as moderate complexity by CLIA. HCPCS code

G0431 was introduced to report more complex testing methods, such as tests that were designated as high complexity under CLIA. Providers were instructed that the new codes should only be reported once per patient encounter. *MLN Matters* SE1105 "Medicare Drug Screen Testing."

72. Although CMS's coding changes were implemented for Medicare billings, state Medicaid programs were not mandated to adopted the changes. As a result, Wisconsin Medicaid incorporated the new HCPCS codes G0434 and G0431, while also continuing to reimburse for drug tests billed with CPT code 80101 and the new CPT code 80104 consistent with the code descriptions provided by CMS and the AMA, respectively.

73. Despite the implementation of CPT code 80104, between January 2011 and November 2012, Acacia and Freund knowingly submitted false claims to Wisconsin Medicaid for each drug class tested with POC cups with CPT code 80101 and recorded a separate unit for each drug class included in the POC cup. Acacia and Freund thereby misrepresented on the nature of the test performed by using CPT code 80101.

74. In September 2011, Wisconsin Medicaid published a notice that it would begin checking claims for laboratory tests against the submitting provider's CLIA certification and would reject claims that were submitted by a provider without the appropriate corresponding CLIA certification. Each CPT and HCPCS code used to bill for a laboratory test is associated with a specific level of CLIA certification. CPT code 80101, which was used by Acacia to bill for tests performed with multiplexed cups, was not identified as a code that could be used to bill for CLIA waived tests, such as the POC cups.

75. In October 2011, after Wisconsin Medicaid issued the above notice, it began denying Acacia's claims submitted with CPT code 80101 because Acacia had only a certificate of waiver and CPT code 80101 was not associated with CLIA waived tests.

76. In response to those denials, Acacia resubmitted claims for the claims that had been denied using HCPCS code G0434, which was a code associated with CLIA waived tests and for which Acacia could only bill one unit. As a result, Acacia's reimbursement for the tests performed with the multiplexed cups dropped from $230 to approximately $20 per test.

77. In November 2011, Freund applied for a CLIA certificate of accreditation on behalf of Acacia. The CLIA certificate of accreditation allows providers to perform complex clinical laboratory testing. In order to obtain that certificate, Freund falsely represented on Acacia's application for accreditation that Acacia owned a particular high complexity laboratory analyzer. However, Acacia never owned that particular high complexity analyzer and did not purchase a similar analyzer until August 2013. In fact, Freund did not intend to perform high complexity at that time. Rather, Freund applied for the CLIA certificate of accreditation so that the Wisconsin Medicaid claims system would pay Acacia's claims for the POC cups using CPT code 80101.

78. After Acacia received its CLIA certificate of accreditation in January 2012, it resumed billing for qualitative tests performed with the POC cups using CPT code 80101 and increased the number of units billed to Medicaid to 13 and 14 units. As a result, Acacia increased its average reimbursement per claim from $20 per claim back up to $253 per claim (above the average reimbursement per claim prior to September 2011).

79. In November 2012, Acacia purchased the VivaE analyzer. After purchasing the analyzer, Acacia and Freund chose to use HCPCS code G0434 for the tests performed with the

POC cups and CPT code 80101 for the tests run on the VivaE analyzer in order to avoid having the claims for these duplicative services denied by the Medicaid billing system. Other than to maximize reimbursement by billing duplicate tests, Freund and Acacia had no reason to change the coding for the tests performed with the POC cups from CPT code 80101 to HCPCS G0434.

80. Finally, Freund and Acacia knew, or recklessly disregarded, the fact that Acacia's confirmatory or quantitative testing of samples between August 2013 and December 2014 was not medically necessary.

81. From at least January 2011 until November 2012 and prior to purchasing the Triple Quad analyzer, Acacia utilized an outside laboratory, Ameritox Labs, to perform quantitative or confirmatory tests on urine samples. Ameritox billed Wisconsin Medicaid directly for any testing it performed on Acacia's patients. While using Ameritox, Acacia sought quantitative testing only with respect to samples that tested positive for one or more substances with POC cups and/or the VivaE analyzer, . demonstrating that Freund and Acacia knew that performing additional testing on negative samples was not necessary. Indeed, since Acacia only provided to Ameritox the positive samples, Ameritox performed quantitative or confirmatory testing on approximately 50% of the tests performed by Acacia.

82. From December 2012 until September 2013, Acacia used another outside laboratory, Quest Diagnostics, to perform quantitative or confirmatory tests on the samples that tested positive for one or more substances with POC cups and/or the VivaE analyzer. Freund instructed the Acacia lab staff to only send to Quest samples that had tested positive on a qualitative test, again demonstrating that Freund knew that performing additional testing on negative samples was not medically necessary. In addition, Quest typically only tested for the

individual substances that tested positive on a qualitative test, rather than testing a panel of substances.

83. After Acacia and Freund spent $200,000 for the Triple Quad analyzer in August 2013, Acacia began performing a panel of quantitative testing on every sample, regardless of whether the sample had tested positive or negative on the qualitative test. Based on the testing policies of the outside laboratories previously utilized by Acacia for quantitative testing, Acacia and Freund knew that testing every sample – including negative samples – for a board panel of substances was not medically necessary.

E. False Claims for Patient A

84. Patient A received health care and mental health services through Acacia from January 2011 until December 2014. Patient A received benefits from Wisconsin Medicaid during part of this time period.

85. Between January 12, 2011 and October 17, 2011, Acacia performed 7 qualitative urine drug screen tests on Patient A using a POC cup and billed those tests to Wisconsin Medicaid.

86. Acacia submitted a claim to Wisconsin Medicaid for each of these tests using CPT code 80101 and recording 12 units of service, falsely representing to Wisconsin Medicaid that 12 separately billable drug classes were tested. Those tests were performed with POC cups and should have been billed using either CPT code 80104 or HCPCS code G0434.

87. In October 2011, Acacia submitted claims to Wisconsin Medicaid for UDSs on two dates of service for Patient A using CPT code 80101, which were denied because Acacia's CLIA certificate of waiver did not permit billing for services using CPT code 80101. After receiving the denials, Acacia resubmitted these claims to Wisconsin Medicaid using HCPCS

code G0434. For each date of service, Acacia submitted 2 claims to Wisconsin Medicaid using HCPCS code G0434, although Patient A's medical records do not contain evidence that two tests were performed on those dates.

88. Acacia received an average of $224 in reimbursement from Wisconsin Medicaid for each test that was allowed using CPT code 80101 between January and October 2011. Acacia received $19.22 in reimbursement from Wisconsin Medicaid for each test that was allowed during this time period using HCPCS code G0434. Acacia was reimbursed $1,200.08 for the claims submitted to Wisconsin Medicaid for Patient A's UDSs during this time period.

89. Each claim submitted between January 12, 2011 and October 17, 2011 using CPT code 80101 and reflecting 12 units were performed was false because (1) it misrepresented the type of test performed as the underlying test was performed with a POC cup and not by a single drug class method; and (2) it misrepresented that 12 separate tests had been performed, when in fact one test had been performed.

90. Between September 1, 2013 through December 11, 2014, Acacia submitted 26 claims to Wisconsin Medicaid for qualitative tests on urine samples given by Patient A on 15 dates.

91. Between September 1, 2013 and December 11, 2014, Acacia submitted 15 claims to Wisconsin Medicaid for quantitative tests on urine samples given by Patient A.

92. Acacia was reimbursed $12,017.97 by Wisconsin Medicaid for urine drug tests on Patient A between September 1, 2013 and December 11, 2014.

93. As to the qualitative tests during this time period, Acacia submitted claims to Wisconsin Medicaid for (1) 10 dates of service using both CPT code 80101 (recording 16 units

or separately billable drug classes) and HCPCS code G0434 and (2) 5 dates of service using only CPT code 80101 (recording 16 units or separately billable drug classes).

94. For each date of service between September 1, 2013 and December 11, 2014, qualitative tests were performed by Acacia on samples given by Patient Awith both a POC cup and the VivaE analyzer. The tests performed with the VivaE analyzer were not medically necessary unless a physician determined that there is a need for a lower detection limit or because the analyzer can test for a particular drug or drug class not available on a POC cup. Because both methods employ the same technology and generate a similar result, the tests are duplicative. Additionally, many of the qualitative tests were not medically necessary because (1) there was no evidence that treatment staff from the clinic reviewed the results and/or addressed positive results with the patient, and (2) the qualitative tests were known to result in false positives for certain drugs being tested. The claims for these medically unnecessary tests were false.

95. As to the quantitative tests during this time period, these tests were not medically necessary because (1) all the urine samples - both those that had tested positive and those that had tested negative on qualitative tests – were tested quantitatively and without a physician determination as to the need for quantitative tests; (2) samples were tested quantitatively for a panel of drugs and there was no individualized determination of what substances should be quantified; and (3) there was no clinical evidence that treatment staff from the clinic reviewed the results of the tests and/or addressed unexpected positive results with the patient.

F. False Claims for Patient B

96. Patient B was a Wisconsin Medicaid member and received health care and mental health services through Acacia from June 2011 to April 2014.

97. Between June 2011 and November 2012, Acacia performed 25 qualitative urine drug screen tests on Patient B using a POC cup.

98. Acacia submitted claims to Wisconsin Medicaid for each of these tests using CPT code 80101 and recording between 12 and 14 units of service, falsely representing to Wisconsin Medicaid that 12 to 14 separately billable drug classes were tested. Those tests were performed with POC cups and should have been billed using either CPT code 80104 or HCPCS code G0434.

99. Between October 2011 and December 2011, Acacia submitted claims to Wisconsin Medicaid on 4 dates of service for Patient B using CPT code 80101 which were denied because Acacia's CLIA certificate of waiver did not permit billing for services using CPT code 80101. After receiving the denials, Acacia resubmitted these claims to Wisconsin Medicaid using HCPCS code G0434. For each date of service, Acacia submitted two claims to Wisconsin Medicaid using HCPCS code G0434, although Patient B's medical records do not contain evidence that two tests were performed on those dates.

100. After Acacia received its CLIA certification of accreditation in January 2012, it resumed submitting claims to Wisconsin Medicaid for urine drug screens performed with a POC cup using CPT code 80101 and increased the number of units or separately billable drug classes to 16.

101. Acacia received an average of approximately $250 in reimbursement from Wisconsin Medicaid for each test that was allowed using CPT code 80101 between June 2011 and November 2012. Acacia received $19.22 in reimbursement from Wisconsin Medicaid for each test that was allowed during this time period using HCPCS code G0434. Acacia was

reimbursed $5,420.70 for the claims submitted to Wisconsin Medicaid for Patient' B's UDSs during this time period.

102. Each claim submitted between June 2011 and November 2012 using CPT code 80101 and reflecting 12 to 16 units were performed was false because (1) it misrepresented the type of test being performed as the underlying test was performed with a POC cup and not by a single drug class method; and (2) it represented that 12 to 16 separate tests had been performed, when in fact one test had been performed.

103. Between December 2012 and August 5, 2013, Acacia performed qualitative tests on samples given by Patient B on 11 dates. On each date, a urine sample from Patient B was tested with both a POC cup and the VivaE analyzer. Both tests are not medically necessary because they are duplicative tests in that they both employ the same technology and generate a similar result. Additionally, many of the qualitative tests were not medically necessary because (1) there was no clinical evidence that treatment staff from the clinic reviewed the results of the tests and/or there was no clinical evidence that treatment staff from the clinic addressed unexpected positive results with the patient, and (2) because the qualitative tests were known to result in false positives and were, therefore, not medically indicated. As a result, the claims submitted by Acacia for these services were false.

104. Between August 13, 2013 and April 2014, Acacia submitted claims to Wisconsin Medicaid for qualitative tests on 11 dates and for quantitative tests on 14 dates on urine samples given by Patient B. Acacia was reimbursed $10,277.96 for these services.

105. For each date of service between August 13, 2013 and April 2014, qualitative tests were performed by Acacia on samples given by Patient B with both a POC cup and the VivaE analyzer. Both tests are not medically necessary because they are duplicative tests in that

they both employ the same technology and generate a similar result. Additionally, many of the qualitative tests were not medically necessary because (1) there is no evidence that treatment staff from the clinic reviewed the results and/or there was no clinical evidence that treatment staff from the clinic addressed unexpected positive results with the patient, and (2) because the qualitative tests were known to result in false positives. The claims for these medically unnecessary tests were false.

106. As to the quantitative tests during this same time period, many of the tests were not medically necessary because (1) samples – both those that had tested positive and those that had tested negative on a qualitative tests – were tested quantitatively and without a physician determination as to the need for a quantitative tests; (2) samples were tested quantitatively for a panel of drugs and there was no individualized determination of what substances should be quantified; (3) there was no clinic evidence that treatment staff from the clinic reviewed the results of the test and/or addressed unexpected positive results with the patient.

VII. ACACIA AND FREUND'S FALSE CLAIMS FOR TELEMEDICINE PSYCHIATRY SERVICES

107. Acacia contracts with physicians to provide psychiatry services to its patients and those physicians primarily provided services to Acacia's clients by telemedicine technology. Telemedicine is the provision of healthcare services by a Medicaid-enrolled provider at a remote location to a patient at an originating site via interactive video and audio.

108. When a claim is submitted to Wisconsin Medicaid for a service that is provided by telemedicine, the provider must include a "GT" modifier with the appropriate CPT code to signify that the service was provided via telemedicine. *Wisconsin Medicaid Mental Health and Substance Abuse Services Handbook* (April 2006); *Forward Health Outpatient Mental Health and Substance Abuse Online Handbook*, Topic 510. For example, if a physician provided 45

minutes of psychotherapy by telehealth, the appropriate code to be included on a claim to Wisconsin Medicaid would be 90806 GT.

109. In December 2010, CMS issued a notice to all states participating in the Medicaid program that the Affordable Care Act of 2010 prohibited payment by any state Medicaid program to telemedicine providers located outside the United States or its territory. Therefore, Congress designated the requirement that a telemedicine provider be located inside the United States as a condition of payment. CMS began enforcing this requirement on June 1, 2011.

110. In accordance with the requirement that telemedicine providers be located inside the United States, HPE (the contractor that processes and pays claims submitted to Wisconsin Medicaid) implemented a policy effective June 1, 2011, to deny claims submitted to Wisconsin Medicaid by providers known to be outside the United States.

111. Wisconsin Medicaid further notified providers via its provider portal that "Wisconsin Medicaid is prohibited from paying providers located outside of the United States and its territories. . . ."

112. The State of Wisconsin further designated this requirement as a condition of payment when it amended the statutory provisions that designate covered mental health services by including a provision that mental health services provided through telehealth may only be reimbursed if the provider is located inside the United States. 2013 Assembly Bill 458, creating Wis. Stat. § 49.45(29w).

113. Because the restriction on providers located outside the United States was directly linked to payment of a claim by such a provider, the location of the provider when providing services was material to Wisconsin Medicaid's payment determination.

114. While Wisconsin Medicaid permits mental health clinics to provide service by telemedicine, it does not permit mental health clinics or providers to facilitate group therapy by telehealth. *Wisconsin Medicaid Mental Health and Substance Abuse Services Handbook* (April 2006); *Forward Health Outpatient Mental Health and Substance Abuse Online Handbook*, Topic 510.

115. Since at least 2010, Acacia and Freund provided psychiatry services to Acacia's patients using, among others, two Medicaid-enrolled physicians, Dr. Isaac Nagel and Dr. Matthew Medwick, who resided primarily in Israel and provided telemedicine services from Israel.

116. Dr. Nagel enrolled as a Wisconsin Medicaid provider in 2010. His application to become a Medicaid provider lists his office address as 6040 W. Lisbon Ave, Milwaukee, Wisconsin, which was Acacia's office location in 2010. Neither Dr. Nagel nor Acacia disclosed to Wisconsin Medicaid that Dr. Nagel was outside the United States when providing services to Acacia's patients by telemedicine.

117. Dr. Medwick enrolled as a Wisconsin Medicaid provider in 2010. His application to become a Medicaid provider lists his office address as 6040 W. Lisbon Ave, Milwaukee, Wisconsin, which was Acacia's office location in 2010. Neither Dr. Medwick nor Acacia disclosed to Wisconsin Medicaid that Dr. Medwick was outside the United States when providing services to Acacia's patients by telemedicine.

118. Acacia knew that Wisconsin Medicaid would not reimburse for services by a provider located outside the United States. Acacia's clinic manager, David Dropkin, received a copy of CMS's notice to the state Medicaid programs on or about May 19, 2011. Accordingly, a

reasonable person would know that Wisconsin Medicaid would not pay for telemedicine service if it knew that the provider was located outside the United States.

119. In addition, Optum Health, an insurance company that contracts with Wisconsin Medicaid to provide Medicaid benefits to Medicaid beneficiaries through a health maintenance organization, denied Acacia's claims for telehealth services provided by the physicians located in Israel in November 2012. In the letter to Freund denying those claims, Optum noted that Dr. Nagel resided outside the United States and stated:

> The review of claims submitted under the name of Isaac Nagel MD showed that Dr. Nagel provided services to Medicaid Subscribers during the portion of the audit period January 1, 2011 thru April 11, 2012. CMS Section 6505: "Prohibition of Payments outside the US" states payments may not be made for services provided by a person outside the United States to a Medicaid subscriber. CMS Section 6505 was effective as of January 1, 2011. Claims submitted showing Dr. Nagel as the rendering practitioner during the described time frame were considered an overpayment.

120. Since July 2011, Acacia and Freund routinely provided psychiatry telemedicine services to its patients through Drs. Nagel and Medwick while they resided in Israel and submitted false claims to the Medicaid program for those services as follows:

Year	Provider Name (Rendering Provider)	Number of Claims	Medicaid Reimbursement
2011	Isaac R Nagel, MD	1,738	$67,232.92
	Matthew B Medwick, MD	0	0.00
	Total	**1,738**	**$67,232.92**
2012	Isaac R Nagel, MD	4,322	$258,906.40
	Matthew B Medwick, MD	711	$25,716.21
	Total	**5,033**	**$284,622.61**
2013	Isaac R Nagel, MD	1,892	$63,695.08
	Matthew B Medwick, MD	859	$26,613.86
	Total	**2,751**	**$90,308.94**
2014	Isaac R Nagel, MD	717	$38,170.10
	Matthew B Medwick, MD	151	$8,717.50
	Total	**868**	**$46,887.60**

2011 – 2014	**Total**	**10,390**	**$489,052.07**

121. In addition, over 60% of the claims submitted by Acacia to Wisconsin Medicaid for the services rendered by Drs. Nagel and Medwick falsely represented that the services were provided in-person because the claims did not include the GT modifier to indicate that the services were provided via telemedicine.

122. Since July 2011, Freund and Acacia submitted false claims to Wisconsin Medicaid for group therapy provided by Drs. Nagel and Medwick while they were outside the United States and did not in fact provide the services.

123. Freund and Acacia knew that Nagel and Medwick were located outside the United States when providing services to Acacia's patients and that the presence of a provider outside the United States was material to Wisconsin Medicaid's payment determination and that Wisconsin Medicaid would not pay for services rendered by a provider located outside the United States.

124. Because Acacia submitted claims to Wisconsin Medicaid that did not disclose that many services provided by Nagel and Medwick were provided by telemedicine or that Nagel and Medwick were in Israel at the time services were provided, Wisconsin Medicaid paid Acacia for claims for services rendered by Nagel and Medwick that it would not have otherwise paid.

A. False Claims for Patient C

125. Patient C received health care and mental health services from Drs. Nagel and Medwick between November 5, 2012 and December 19, 2013.

126. From November 5, 2012 through December 19, 2013, Acacia submitted 15 claims for services provided to Patient C purportedly by Drs. Nagel and Medwick, including the following:

- An office consultation with Dr. Nagel on November 5, 2012;
- An office consultation with Dr. Medwick on November 6, 2012;
- Three group psychotherapy sessions on November 13, 20, and December 5, 2012; and
- Eight office visits on November 20 and 27, 2012; December 5 and 11, 2012; January 8 and 22, 2013; and February 5 and 19, 2013.

127. Drs. Nagel and Medwick were in Israel when these services were provided via telemedicine.

128. While these services were provided by telemedicine, the "GT" modifier was not appended to any of the codes used to bill these services.

129. In addition, the group psychotherapy services billed by Dr. Nagel and as specified above, were not, in fact, provided by Dr. Nagel but were provided by counselors-in-training who were employed by Acacia.

130. Acacia submitted claims to Wisconsin Medicaid for the services in Paragraph 126, above, and was reimbursed $853.76.

131. The claims submitted by Acacia were false because the Wisconsin Medicaid rules prohibit payment for telemedicine services provided by providers located outside the United States and because the claims for the group therapy services misrepresent who provided the therapy services.

B. False Claims for Patient D

132. Patient D received health care and mental health services from Dr. Nagel between December 12, 2012 and July 7, 2014.

133. From December 12, 2012 to July 7, 2014, Acacia submitted 21 claims for services provided by Dr. Nagel to Patient D, including the following:

- One psychotherapy visit on December 7, 2012;
- One medication management visit on December 20, 2012; and
- Nineteen office visits on January 28, February 25, April 22, May 1, May 29, June 26, July 24, August 21, October 3, October 23, and November 25, 2013; and January 9, February 6, February 20, March 3, March 18, May 13, June 9, and July 7, 2014.

134. Dr. Nagel was in Israel while providing these services via telemedicine.

135. While these services were provided by telemedicine, the "GT" modifier was appended to only 9 of the claims for these 21 services, thereby misrepresenting that these services were provided in Acacia's clinic in Milwaukee, Wisconsin.

136. Acacia submitted claims to Wisconsin Medicaid for the services in Paragraph 133, above, and was reimbursed $1,033.54.

137. The claims submitted by Acacia were false because the Wisconsin Medicaid rules prohibit payment for telemedicine services provided by providers located outside the United States.

VIII. CLAIMS FOR RELIEF

A. Count One: False Claims Act, 31 U.S.C. § 3729(a)(1)(A)

138. Plaintiff United States repeats and re-alleges each allegation in each of the preceding paragraphs as if fully set forth herein.

139. Freund and Acacia submitted and/or caused to be submitted false claims for payment to Wisconsin Medicaid seeking reimbursement for (1) drug tests performed with point-of-care cups but billed as if they were performed with more complex equipment; (2) duplicative drug tests; (3) medically unnecessary urine drug tests, (4) drug tests for which there is no clinical document of the test, and (4) psychiatric services provided by physicians located outside the United States. Freund and Acacia knowingly submitted or caused the submission of false and ineligible claims to Wisconsin Medicaid in violation of the False Claims Act.

140. By virtue of the false or fraudulent claims that Freund and Acacia submitted or caused to be submitted, the United States and the State of Wisconsin have suffered actual damages and are entitled to recover treble damages plus a civil monetary penalty for each false claim.

B. Count Two: False Claims Act, 31 U.S.C. § 3729(a)(1)(B)

141. Plaintiff United States repeats and re-alleges each allegation in each of the preceding paragraphs as if fully set forth herein.

142. Freund and Acacia knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims to Wisconsin Medicaid. Specifically, Freund and Acacia knowingly created false billing records that (1) misrepresented the drug tests that were performed, (2) misrepresented that psychiatry services had been provided in Acacia's

clinic and not by telehealth; and (3) misrepresented that other telehealth services had been appropriately provided by physicians located inside the United States.

C. Count Three: Unjust Enrichment

143. Plaintiff United States repeats and re-alleges each allegation in each of the preceding paragraphs as if fully set forth herein.

144. The United States claims the recovery of all monies by which Freund and Acacia have been unjustly enriched, including profits earned by Freund and Acacia because of the conduct described herein.

145. By retaining the monies received for the conduct described herein, Freund and Acacia were unjustly enriched at the expense of the United States and the State of Wisconsin in an amount to be determined and, which in equity and good conscience, should be returned to the United States and the State of Wisconsin.

IX. PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in favor of the United States as follows:

1. On Counts One and Two under the False Claims Act, for the amount of the United States' and the State of Wisconsin's damages, trebled as required by law, and such civil penalties as are required by law, together with such further relief as may be just and proper.

2. On Count Three for unjust enrichment, for the damages sustained and/or amounts by which Freund and Acacia, retained illegally obtained monies, plus interest, costs, and expenses, and such further relief as may be just and proper.

The United States demands a jury trial on each of the issues so triable in this case.

Dated this 28th day of December, 2016.

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